



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3463]

Aurolife Pharma, LLC, et al.; Withdrawal of Approval of Seven Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of seven abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945, Trang.Tran@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 072112	Clorazepate Dipotassium Capsules, 3.75 milligrams (mg), 7.5 mg, and 15 mg	Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520
ANDA 074863	Clemastine Fumarate Syrup, Equivalent to (EQ) 0.5 mg base/5 milliliters (mL)	Workhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053
ANDA 080925	Isocaine 3% (mepivacaine hydrochloride (HCl)) Injection USP, 3%	Septodont, Inc., c/o Arent Fox, LLP, 1717 K St., NW, Washington, DC 20006
ANDA 084048	Octocaine (lidocaine HCl and epinephrine) Injection USP, 2%; 0.01 mg/mL and 2%; 0.02 mg/mL	Do.
ANDA 084697	Isocaine 2% (mepivacaine HCl and levonordefrin) Injection USP, 2%; 0.05 mg/mL	Do.
ANDA 086033	Isosorbide Dinitrate Sublingual Tablets USP, 2.5 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 087504	Chloroquine Phosphate Tablets USP, EQ 150 mg base	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: September 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-20947 Filed: 9/25/2018 8:45 am; Publication Date: 9/26/2018]